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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,689	01/10/2002	Peter P. Lee	016976-000220US	7712

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,689	LEE, PETER P.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-35,37 and 38* is/are pending in the application.

4a) Of the above claim(s) *29-35, 37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/10/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made with respect to the amendment to the first line of the specification updating the priority of the instant application, submitted January 10, 2002. In addition, acknowledgement is made of the amendment to the title of the instant application submitted March 19, 2004.

Election/Restrictions

Applicant's election without traverse of group I, claims 17-28 in the response submitted March 19, 2004 is acknowledged.

Claims 17-35, 37 and 38 are pending in the application. Claims 29-35, 37 and 38 are withdrawn from consideration due to a non-elected invention and claims 17-28 are under consideration.

Claims 17-28 are drawn to an elected product.

The following is a recitation of M.P.E.P. § 821.04, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined . If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.
>
> In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office

> action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.E.P. § 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-20 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick et al. (Journal of Immunology. 1997; 158: 3474-3482) and Meruelo et al. (US 5,834,589).

The claims are drawn to a chimeric molecule comprising a viral-specific ligand and a bacterial-specific ligand, where the bacterial-specific ligand binds to bacteria that is an inhabitant of a mucosal membrane. Both viral and bacterial-specific ligands are antibodies or comprise a protein or polypeptide. The viral-specific ligand is comprises CD4 or CD21 and is a single chain antibody or F(ab). The claims also require that the chimeric molecule in a sterile solution or a physiologically acceptable carrier.

McCormick et al. teach a cross-linked bispecific antibody (PHMAD8-60.3) comprising:

1) a monoclonal antibody specific for the O-specific side chain of opsinized *Pseudomonas aeruginosa* (Pa), a bacterium that infects the lungs, and

2) a monoclonal antibody specific for CD18.

See the abstract, "Formation of Heteroconjugates" on page 3475 and "Construction of bispecific Ab heteroconjugates", Figure 1, "Confirmation of heteroconjugate binding....", "Confirmation of heteroconjugate binding to PMN and specificity for CD18" and "Effects of bsAb on Pa...", bridging pages 3476-3477. Monoclonal antibodies are a specific species of proteins.

Although McCormick et al. do not teach the carrier the bispecific antibody is suspended in, it is conventional laboratory practice to perform assays under sterile conditions. Further, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to formulate the bispecific antibody in a pharmaceutically acceptable carrier to treat Pa infection in cystic fibrosis patients. One of ordinary skill in the art would have had a reasonable expectation of success for combining the bispecific antibody of McCormick et al. into a pharmaceutically

acceptable carrier because McCormick et al. teach the delivery of the bispecific antibody to human cells, see the previous citations.

McCormick et al. do not teach a viral-specific ligand.

Meruelo et al. teach chimeric viral receptor proteins comprising single chain antibody fragments of specific for a human cell, see claim 1 for example. The human cell viral receptors of Meruelo et al. encompass CD4, an HIV viral receptor, see column 2, lines 46-55, and CD21, an oral mucosa receptor for Epstein-Barr virus, see column 5, lines 46-47.

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to substitute an antibody to the cell surface receptor, CD18, of McCormick et al. for a cell surface receptor, such as CD4 or CD21 of Meruelo et al. to target tissue-specific cells in the mucosa, such as those that express CD21, or to inhibit viral infection, see column 4, line 58 to column 6, line 61 of Meruelo et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for exchanging the antibody of a cellular receptor of McCormick et al. with another antibody to a cellular viral receptor, taught by Meruelo et al. because both references teach bispecific antibodies comprising cellular receptors, see pages 3475-3477 of McCormick et al. and column 6, lines 26-39 of Meruelo et al., for example.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick et al. and Meruelo et al. as applied to claims 17-20 and 23-28 above, and further in view of Baba et al. (EMBO Journal. 1996; 15 (18): 4789-4797, provided in the IDS).

The claims require that the bacterial-specific ligand is the C-terminal domain of lysostaphin and that the targeted bacteria is *Staphylococcus*.

See the teachings of McCormick et al. and Meruelo et al. above. Neither reference teaches the C-terminal domain of lysostaphin or targeting *Staphylococcus*.

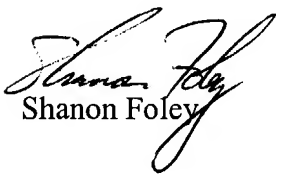
However, Baba et al. teach target specificity to *Staphylococcus aureus* with C-terminal lysostaphin residues, see the abstract and "Targeting of hybrid proteins..." bridging pages 4790-4792. One of ordinary skill in the art at the time the invention was made would have been motivated to substitute the Pa bacterial-specific portion of the bispecific antibody of McCormick et al. for the C-terminus of lysostaphin, taught by Baba et al. to target *S. aureus* infections in cystic fibrosis patients, see the first paragraph of the introduction of McCormick et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for substituting the Pa-specific portion of the bispecific antibody of McCormick et al. for lysostaphin fragment of Baba et al. because both references teach bispecific molecules comprising bacterial-specific fragments that specifically target bacteria in the mucosa, see the previous citations of McCormick et al. and the "Results" section and "Targeting of GST-CWT" on page 4796 of Baba et al. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shanon Foley